K081057

510(k) SUMMARY

JUN 17 2008

Intact Medical Corporation's ***Intact***® Excision XL

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Doug Macarthur
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Date Prepared: April 11, 2008

Name of Device and Name/Address of Sponsor

Common or Usual Name:	Electrosurgical Generator
Trade or Proprietary Name:	***Intact***® Excision XL
Classification Name:	Electrosurgical Cutting & Coagulation Device & Accessories (21 C.F.R. § 878.4400) Biopsy Instrument (21 C.F.R. § 876.1075)

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Predicate Devices

Intact Medical (formerly Neothermia) Corp.'s ***Intact***® BLES and ***Intact***® Advance (formerly en-bloc Biopsy) System (K060413).

Intended Use

The ***Intact***® Excision XL is indicated to provide tissue samples for diagnostic sampling of breast abnormalities.

The ***Intact***® Excision XL is intended to provide breast tissue for histologic examination with partial or complete removal of an imaged abnormality.

The ***Intact***® Excision XL is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpable or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the *intact*™ system may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histologic evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2008

Intact Medical Corporation
% Mr. Doug Macarthur
Senior Director of Engineering
One Apple Hill, Suite 316
Natick, Massachusetts 01760

Re: K081057
Trade/Device Name: *Intact*® Excision XL
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: April 11, 2008
Received: April 14, 2008

Dear Mr. Macarthur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081057

Device Name: ***Intact***® Excision XL

Indications For Use:

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In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the ***Intact***® System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histologic evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Prescription Use _____x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil R. Ogden for MRN

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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